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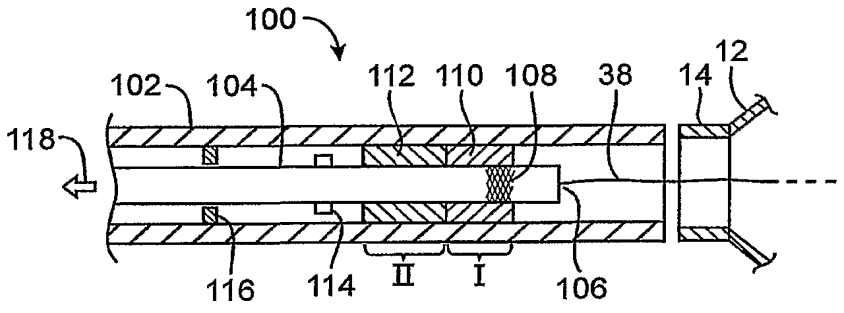
(54) Title: SYSTEM FOR OPTIMIZING ANCHORING FORCE



(57) Abstract: Systems for optimizing anchoring force are described herein. In securing tissue folds, over-compression of the tissue directly underlying the anchors is avoided by utilizing tissue anchors having expandable arms configured to minimize contact area between the anchor and tissue. When the anchor is in its expanded configuration, a load is applied to the anchor until it is optimally configured to accommodate a range of deflections while the anchor itself exerts a substantially constant force against the tissue. Various devices, e.g., stops, spring members, fuses, strain gauges, etc., can be used to indicate when the anchor has been deflected to a predetermined level within the optimal range. Moreover, other factors to affect the anchor characteristics include, e.g., varying the number of arms or struts of the anchor, positioning of the arms, configuration of the arms, the length of the collars, etc.

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SYSTEM FOR OPTIMIZING ANCHORING FORCE

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is related to U.S. Pat. App. Serial Nos. 10/865,736 (Attorney docket no. 021496-001700US), and 10/865,243 (Attorney Docket No. 021496-001800US), each of which were filed on June 9, 2004.

BACKGROUND OF THE INVENTION

[0002] 1. Field of the Invention. The present invention relates to apparatus and methods for optimizing the force for securing anchors against tissue. More particularly, the present invention relates to apparatus and methods for optimizing the force for loading basket-type anchors within or against tissue within a body.

[0003] Morbid obesity is a serious medical condition pervasive in the United States and other countries. Its complications include hypertension, diabetes, coronary artery disease, stroke, congestive heart failure, multiple orthopedic problems and pulmonary insufficiency with markedly decreased life expectancy.

[0004] A number of surgical techniques have been developed to treat morbid obesity, e.g., bypassing an absorptive surface of the small intestine, or reducing the stomach size. However, many conventional surgical procedures may present numerous life-threatening post-operative complications, and may cause atypical diarrhea, electrolytic imbalance, unpredictable weight loss and reflux of nutritious chyme proximal to the site of the anastomosis.

[0005] Furthermore, the sutures or staples that are often used in these surgical procedures typically require extensive training by the clinician to achieve competent use, and may concentrate significant force over a small surface area of the tissue, thereby potentially causing the suture or staple to tear through the tissue. Moreover, the tissue underlying the suture or staple may be subject to becoming over-compressed to the point of becoming subject to necrosis. Many of the surgical procedures require regions of tissue within the body to be approximated towards one another and reliably secured without necrosing the approximated tissue. The gastrointestinal lumen includes four tissue layers, wherein the

mucosa layer is the inner-most tissue layer followed by connective tissue, the muscularis layer and the serosa layer.

[0006] One problem with conventional gastrointestinal reduction systems is that the anchors (or staples) should engage at least the muscularis tissue layer in order to provide a proper foundation. In other words, the mucosa and connective tissue layers typically are not strong enough to sustain the tensile loads imposed by normal movement of the stomach wall during ingestion and processing of food. In particular, these layers tend to stretch elastically rather than firmly hold the anchors (or staples) in position, and accordingly, the more rigid muscularis and/or serosa layer should ideally be engaged. This problem of capturing the muscularis or serosa layers becomes particularly acute where it is desired to place an anchor or other apparatus transesophageally rather than intraoperatively, since care must be taken in piercing the tough stomach wall not to inadvertently puncture adjacent tissue or organs. Thus, an anchor is desirably non-traumatic to the surrounding tissue. Moreover, the anchor is also desirably strong enough to withstand the movement of the tissue.

[0007] One conventional method for securing anchors within a body lumen to the tissue is to utilize sewing devices to suture the stomach wall into folds. This procedure typically involves advancing a sewing instrument through the working channel of an endoscope and into the stomach and against the stomach wall tissue. The contacted tissue is then typically drawn into the sewing instrument where one or more sutures or tags are implanted to hold the suctioned tissue in a folded condition known as a plication. Another method involves manually creating sutures for securing the plication.

[0008] One of the problems associated with these types of procedures is the time and number of intubations needed to perform the various procedures endoscopically. Another problem is the time required to complete a plication from the surrounding tissue with the body lumen. In the period of time that a patient is anesthetized, procedures such as for the treatment of morbid obesity or for GERD must be performed to completion. Accordingly, the placement and securement of the tissue plication should ideally be relatively quick and performed with a minimal level of confidence.

[0009] Another problem with conventional methods involves ensuring that the staple, knotted suture, or clip is secured tightly against the tissue and that the newly created plication will not relax under any slack which may be created by slipping staples, knots, or clips. Other conventional tissue securement devices such as suture anchors, twist ties, crimps, etc.

are also often used to prevent sutures from slipping through tissue. However, many of these types of devices are typically large and unsuitable for low-profile delivery through the body, e.g., transesophageally. Moreover, these methods do not allow the surgeon to gauge the amount of force being applied to or against the tissue by the sutures, staple, clip, etc. Thus, over-tightening of the tissue anchor against the underlying tissue surface may be problematic.

[0010] Moreover, when grasping or clamping onto or upon the layers of tissue with conventional anchors, sutures, staples, clips, etc., many of these devices are configured to be placed only after the tissue has been plicated and not during the actual plication procedure.

BRIEF SUMMARY OF THE INVENTION

[0011] In securing the tissue folds or anchoring to or from these tissue folds or plications, over-compression of the tissue directly underlying the tissue anchors is preferably avoided. Over-compression of the underlying tissue may occur if the anchor compresses the tissue to such a degree that tissue necrosis or cutting of the underlying muscularis or serosal tissue by the anchor occurs. Accordingly, a tissue anchor is preferably configured to maintain or secure a tissue plication yet still allow for adequate blood flow to occur within the tissue underlying the anchor. As such, the tissue anchor is preferably configured to accommodate a range of deflections due to various movements of the tissue due to, e.g., peristalsis, patient movement, weight of the gastrointestinal organ itself, etc., while maintaining or exerting a substantially constant force against the tissue.

[0012] A particular type of anchor which may be utilized is a reconfigurable "basket"-type anchor generally having a number of configurable struts or legs extending between at least two collars or bushing members. This anchor may have a low-profile delivery configuration and a radially expanded anchoring configuration. When expanded, each arm of the anchor may be separated from one another by a spacing or opening. The spacing is preferably created to minimize the contact area between the anchor body and the underlying tissue surface to allow for greater blood flow in the tissue and to inhibit necrosis of the tissue.

[0013] The anchor may be made from various materials, e.g., spring stainless steel, plastics such as polyurethane, nylon, etc., but is preferably made from a shape memory or superelastic alloy, e.g., Nitinol. The anchor may thus be shaped and heat-set such that it self-forms or automatically configures itself from the delivery configuration to the expanded configuration upon release of a constraining force, e.g., when the anchor is ejected from its delivery needle

or catheter. Sutures may connect a proximal anchor to a distal anchor through the tissue fold to secure the plication.

[0014] When the anchor has been configured into its expanded configuration, a load or force may be applied to the anchor until the anchor has been optimally configured to accommodate a range of deflections while the anchor itself maintains or exerts a substantially constant force against the tissue. Anchor deflection may occur, e.g., when the proximal and distal collars of an anchor have been advanced or urged towards one another such that the arms or struts extending therebetween are at least partially deflected. Moreover, anchor deflection may be due to various movements of the tissue attributable to, e.g., peristalsis, patient movement, weight of the gastrointestinal organ itself, etc.

[0015] Knowing the anchor deflection-to-exerted force characteristics for a given anchor, one may load an anchor with a tension or compression force such that subsequent deflections of the underlying tissue being anchored occur within specified ranges, such as the optimal range. For instance, an anchor may be pre-loaded such that tissue fluctuations or movements occur within the optimal window or range where the force exerted by the anchor remains relatively constant over a range of deflections. This in turn may ensure that the underlying tissue is not subject to over-compression by the anchors.

[0016] One method for limiting the loading or pre-load force upon an anchor may involve including a post or stop in the anchor body which limits the proximal deflection of the distal collar and thus prevents over-compression of the anchor against the tissue. Another variation may utilize friction-producing regions within the anchor delivery catheter. As the anchor is tensioned, various regions may produce frictional forces which vary in accordance to the degree of anchor deflection. A change in the detected frictional force may thus be utilized to indicate that anchor has been configured within an optimal range of deflections.

[0017] Another variation may include the use of a spring member having a known spring constant or fuse-like member which are set to break or fail at predetermined levels of detected force to detect the amount of deflection an anchor has undergone. Alternatively, measurement of material deformation via strain gauges may also be utilized to determine the amount of deflection. The anchor tensioning assembly may thus be configured to indicate when the anchor has been deflected to a predetermined level, when the anchor has been deflected within the optimal range.

[0018] Yet another variation may include configuring the proximal collar of the anchor to prevent the passage of stop member contained within the anchor. thus, the length of suture extending from the stop member to the attachment point within the anchor may be of a predetermined length such that when the stop member is seated against the proximal collar, the suture length may compress the anchor into a predetermined deflection level. This deflection level may be preset to configure the anchor to any desired configuration, as described above.

[0019] The anchors may be tensioned through various methods. One particular method may include tensioning the anchors via an elongate rigid or flexible shaft having a hollow lumen. A tensioning mechanism, which is configured to receive the anchors and grasp a tensioning suture, may be positioned near or at the distal end of the elongate shaft. After the anchor or anchors have been desirably tensioned, the shaft may simply be removed from the body.

[0020] Various other factors of the tissue anchors may be modified to affect the tensioning and loading characteristics when deflecting the anchors. Moreover, some of the factors may also affect the interaction of the anchor with respect to the tissue in ensuring that the tissue is not over-compressed and that adequate blood flow may occur within the tissue directly beneath the anchor. Some of the factors may include, e.g., varying the number of arms or struts of the anchor, positioning of the arms, configuration of the arms, the length of the collars, etc.

[0021] Moreover, exposed portions of the anchor may be optionally coated or covered with a material to protect against exposure to foreign materials, e.g., food or other object which may be ingested by the patient, other surgical tools, etc. Accordingly, a biocompatible coating or covering may be placed over the entire length of the anchor arms or only along the portions of the arms not against the tissue. Alternatively, a mesh or skirt-like covering may be placed over the exposed portion of the anchor or the entire anchor itself may be covered with a distensible or expandable covering or mesh.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] Figs. 1A and 1B show perspective views of an example of a basket-type anchor in a delivery configuration and an expanded configuration, respectively.

[0023] Fig. 2A shows a cross-sectional side view of one variation for delivering a basket. anchor through a needle for anchoring to a fold of tissue.

[0024] Fig. 2B shows a cross-sectional side view of examples of how basket anchors may be utilized in anchoring tissue plications.

[0025] Figs. 3A and 3B show a graph of initial displacement or deflection versus exerted force and an example of a tissue anchor correspondingly displaced, respectively.

[0026] Figs. 4A and 4B show the graph illustrating an optimal range of anchor deflection where the exerted force by the anchor remains substantially constant and the correspondingly compressed anchor, respectively.

[0027] Figs. 5A and 5B show the graph illustrating the rising force for an over-compressed anchor and the correspondingly compressed anchor, respectively.

[0028] Figs. 6A and 6B show cross-sectional side views of an anchor having a center post extending within the anchor for limiting the compression of the anchor.

[0029] Figs. 7A and 7B show cross-sectional side views of one variation of an anchor tensioning or loading mechanism utilizing different frictional coefficients to indicate the load placed upon the anchor.

[0030] Figs. 8A and 8B show the corresponding frictional force generated utilizing the device of Figs. 7A and 7B, respectively.

[0031] Fig. 9 shows a partial cross-sectional view of another variation of an anchor loading mechanism which utilizes a spring member having a known spring constant.

[0032] Fig. 10 shows a partial cross-sectional view of another variation of an anchor loading mechanism utilizing a strain gauge for measuring the strain, and the resultant load, exerted upon the anchor.

[0033] Fig. 11 shows a cross-sectional view of another variation of an anchor loading mechanism which utilizes a stop for limiting the anchor compression to a predetermined limit.

[0034] Figs. 12A and 12B show partial cross-sectional views of another variation of an anchor loading mechanism utilizing a fuse-like device set to break or release upon reaching a predetermined load.

[0035] Figs. 13A and 13B show side views of various notched fuse-members which may be utilized with the variation of Figs. 12A and 12B.

[0036] Fig. 14A shows a partial cross-sectional side view of a device which may be used to apply the load upon the loading mechanism.

[0037] Fig. 14B shows a perspective view of an alternative loading mechanism.

[0038] Fig. 14C shows a side view of an assembly in which the loading mechanism may be placed for applying the load upon the anchors.

[0039] Figs. 15A and 15B show side and edge views, respectively, of one variation of a basket anchor in a flattened and splayed view

[0040] Fig. 15C shows a perspective view of the anchor of Figs. 15A and 15B in its delivery configuration.

[0041] Figs. 16A and 16B show side and edge views, respectively, of another variation of a basket anchor in a flattened and splayed view

[0042] Fig. 16C shows a perspective view of the anchor of Figs. 16A and 16B in its delivery configuration.

[0043] Figs. 17A to 17J show cross-sectional end views of the proximal (I), middle (II), and distal (III) portions of a single anchor strut or arm showing some of the various shapes that the anchor strut or arm may be configured.

[0044] Figs. 18A to 18F show examples of end views of anchors having an increasing number of struts or arms.

[0045] Figs. 19A to 19F show examples of side views of anchors having various strut or arm configurations.

[0046] Figs. 20A and 20B show side views of anchors having various configurations affected by the heights of the anchor collars.

[0047] Fig. 21A shows a perspective view of an anchor in an expanded configuration having a protective coating or covering over at least a portion of the struts or arms.

[0048] Fig. 21B shows a perspective view of another anchor having a protective covering or mesh over at least a portion of the anchor facing away from the tissue surface.

[0049] Fig. 21C shows a perspective view of another anchor having a protective covering or mesh over the entire anchor body.

DETAILED DESCRIPTION OF THE INVENTION

[0050] Generally, in creating and securing a plication within a body lumen of a patient, various methods and devices may be implemented. The anchoring and securement devices may be delivered and positioned via an endoscopic apparatus that engages a tissue wall of the gastrointestinal lumen, creates one or more tissue folds, and disposes one or more of the anchors through the tissue fold(s).

[0051] In securing the tissue folds or anchoring to or from these tissue folds or plications, over-compression of the tissue directly underlying the tissue anchors is preferably avoided. Over-compression of the underlying tissue may occur if the anchor compresses the tissue to such a degree that tissue necrosis or cutting of the underlying muscularis or serosal tissue by the anchor occurs. The anchor preferably exerts a force, e.g., about 0.1 - 0.5 lbs, sufficient to maintain or secure a tissue plication yet still allows for adequate blood flow to occur within the tissue underlying the anchor. Accordingly, the tissue anchor is preferably configured to accommodate a range of deflections due to various movements of the tissue due to, e.g., peristalsis, patient movement, weight of the gastrointestinal organ itself, etc., while maintaining or exerting a substantially constant force against the tissue.

[0052] Formation of a tissue fold may be accomplished using at least two tissue contact areas that are separated by a linear or curvilinear distance, wherein the separation distance between the tissue contact points affects the length and/or depth of the fold. In operation, a tissue grabbing assembly engages or grasps the tissue wall in its normal state (i.e., non-folded and substantially flat), thus providing a first tissue contact area. The first tissue contact area then is moved to a position proximal of a second tissue contact area to form the tissue fold. The tissue anchor assembly then may be extended across the tissue fold at the second tissue contact area. Optionally, a third tissue contact point may be established such that, upon formation of the tissue fold, the second and third tissue contact areas are disposed on opposing sides of the tissue fold, thereby providing backside stabilization during extension of the anchor assembly across the tissue fold from the second tissue contact area.

[0053] The first tissue contact area may be utilized to engage and then stretch or rotate the tissue wall over the second tissue contact area to form the tissue fold. The tissue fold may then be articulated to a position where a portion of the tissue fold overlies

the second tissue contact area at an orientation that is substantially normal to the tissue fold. A tissue anchor may then be delivered across the tissue fold at or near the second tissue contact area. One apparatus which is particularly suited to deliver the anchoring and securement devices described herein may be seen in further detail in co-pending U.S. Pat. App. Serial No. 10/735,030, filed December 12, 2003, which is incorporated herein by reference in its entirety.

[0054] Various tissue anchors may be utilized for securing the tissue plications within the lumen. For instance, examples of tissue anchors which may be utilized are disclosed in co-pending U.S. Pat. App. Serial No. 10/612,170, filed July 1, 2003, which is incorporated herein by reference in its entirety. Moreover, a single type of anchor may be used exclusively in an anchor assembly; alternatively, a combination of different anchor types may be used in an anchor assembly. One particular type of anchor described herein is a reconfigurable "basket"-type anchor, which may generally comprise a number of configurable struts or legs extending between at least two collars or bushing members.

[0055] As described below, a system for loading an anchor for placement against a tissue surface may generally comprise an anchor body having a delivery configuration and an expanded configuration adapted for placement against the tissue surface, and a loading mechanism in communication with the anchor body, wherein the loading mechanism is adapted to indicate a loading condition upon the anchor body.

[0056] One particular illustrative basket anchor is shown in the perspective views of Figs. 1A and 1B. Fig. 1A shows deformable basket anchor **10** in a low-profile delivery configuration having proximal collar or bushing **14** and distal collar or bushing **16** with a plurality of struts or arms **12** extending between collars **14, 16.** Each arm **12** may be separated from one another by spacing or opening **20.** Moreover, each arm **12** may be aligned parallel with one another although this is not necessary. Anchor **10** may define lumen **18** through the length of anchor **10** to allow for the passage of one or more sutures therethrough.

[0057] Fig. 1B shows a perspective view of anchor **10** of Fig. 1A in an anchoring or expanded configuration **10'.** In such a configuration, proximal collar **14** and distal collar **16** are advanced towards one another such that the middle section **22** of arms **12** extend radially outwardly. Anchor **10'** may be made from various materials, e.g., spring stainless steel, but is preferably made from a shape memory or superelastic alloy, e.g.,

nitinol. The anchor may thus be shaped and heat-set such that it self-forms or automatically configures itself from the delivery configuration **10** to the expanded configuration **10'** upon release of a constraining force, e.g., when the anchor is ejected from its delivery needle or catheter, as described further below. Alternatively, the anchor may be configured to self-form into its expanded configuration **10'** upon the application of some activation energy to the anchor, e.g., electrical energy, heat from the surrounding tissue, etc.

[0058] Upon expanding, the arms **12** of anchor **10'** may extend radially outwardly such that spacing or opening **20'** is defined between adjacent arms **12**. The spacing **20'** is preferably created to minimize the contact area between the anchor body and the underlying tissue surface to allow for greater blood flow in the tissue and to inhibit necrosis of the tissue.

[0059] When anchor **10'** contacts the tissue surface, proximal collar **14** and proximal section **24** of arm **12** lay against the tissue while distal section **26** of arm **12** extends away from the tissue surface. Although seven arms **12** are shown in this example, the number of arms is not intended to be limiting and may be varied, as described in further detail below. Moreover, the configurations of proximal **24**, distal **26**, and middle section **22** of arms **12** may also be varied and is also described in further detail below.

[0060] Deploying the anchors against, into, or through the tissue may be accomplished in a number of ways. One example is shown in Fig. 2A, which shows a cross-section of an anchor delivery system **30** in proximity to tissue fold **F**. Tissue fold **F** may comprise a plication of tissue created using any number of tissue plication devices. Examples of such devices which may be utilized are described in further detail in U.S. Pat. App. Serial No. 10/735,030, filed December 12, 2003. Tissue fold **F** may be disposed within a gastrointestinal lumen, such as the stomach, where tissue wall **W** may define the outer or serosal layer of the stomach. The anchor delivery assembly may generally comprise launch tube **32** and needle **40** slidingly disposed within the launch tube lumen. Needle **48** may generally be configured as a hollow needle having a tapered or sharpened distal end to facilitate its travel into and/or through the tissue.

[0061] Delivery push tube or catheter **34** may be disposed within launch tube **32** proximally of basket anchor **10**, which is shown in a compressed delivery configuration with a relatively low profile when disposed within needle lumen **42** of needle **40**. A

single basket anchor **10** is shown disposed within needle **40** only for illustrative purposes and is not intended to be limited by the number of basket anchors; rather, any number of basket anchors may be disposed within needle lumen **42** as practicable depending upon the desired procedure and anchoring results.

[0062] Once launch tube **32** has been desirably positioned with respect to tissue fold **F**, needle **40** may be urged or pushed into or through tissue fold **F** via needle pushrod or member **44** from its proximal end. As shown in Fig. 2B, basket anchor **56** has been urged or ejected from needle **40** and is shown in its radially expanded profile for placement against the tissue surface. In such a case, a terminal end of suture **66** may be anchored within the distal collar of anchor **64** and routed through tissue fold **F** and through, or at least partially through, proximal anchor **56**, where suture **38** may be cinched or locked proximally of, within, or at proximal anchor **56** via any number of cinching or locking mechanisms **68**. Proximal anchor **56** is also shown in a radially expanded profile contacting tissue fold **F** along tissue contact region **54**. Locking or cinching of suture **38** proximally of proximal anchor **56** enables the adequate securement of tissue fold **F**.

[0063] A single suture or flexible element **38** (or multiple suture elements) may connect proximal anchor **56** and distal anchor **64** to one another through tissue fold **F** in the case of a single tissue fold **F**. If additional tissue folds are plicated for securement, distal anchor **46** may be disposed distally of at least one additional tissue fold **F'** while proximal anchor **56** may be disposed proximally of tissue fold **F**. As above, suture **38** may be similarly affixed within distal anchor **46** and routed through proximal anchor **56**, where suture **38** may be cinched or locked via cinching or locking mechanism **68**, as necessary. Locking mechanism **68** may be further configured to apply a locking force upon the suture **38** such that the anchors located upon both sides of tissue fold **F** (or tissue folds **F** and **F'**) may be advanced towards one another while cinching the tissue plication(s). Suture or flexible element **38** may comprise various materials such as monofilament, multifilament, or any other conventional suture material, elastic or elastomeric materials, e.g., rubber, etc.

[0064] If tissue folds **F** and **F'** are to be positioned into apposition with one another, distal anchor **46** and proximal anchor **56** may be approximated towards one another. Proximal anchor **56** is preferably configured to allow suture **38** to pass freely therethrough during the anchor approximation. However, proximal anchor **56** is also

preferably configured to prevent or inhibit the reverse translation of suture **38** through proximal anchor **56** by enabling uni-directional travel of anchor **56** over suture **38**. This cinching feature thereby allows for the automated locking of anchors **46, 56** relative to one another during anchor approximation. Aspects of anchor positioning relative to tissue and various examples of cinching or locking mechanisms may be seen in further detail in U.S. Pat. App. Serial Nos. 10/840,950 filed 05/07/2004 (Attorney Docket No. 021496-000900 US); 10/841,245 filed 05/07/2004 (Attorney Docket No. 021496-001000 US); 10/840,951 filed 05/07/2004 (Attorney Docket No. 021496-001100 US); and 10/841,411 filed 05/07/2004 (Attorney Docket No. 021496-001200 US), all of which were filed May 7, 2004 and each of which is incorporated herein by reference in its entirety.

[0065] The anchors, as described above, may be seen in Fig. 2B to each have proximal collars **48, 58** and respective distal collars **50, 60** with struts or arms **52, 62** extending therebetween. As described above, the basket anchors are preferably reconfigurable from a low profile delivery configuration to a radially expanded deployment configuration in which a number of struts, arms, or mesh elements may radially extend once released from launch tube **32** or needle **40**. Materials having shape memory or superelastic characteristics or which are biased to reconfigure when unconstrained are preferably used, e.g., spring stainless steels, Ni-Ti alloys such as Nitinol, etc.

[0066] The basket anchors are illustrated as having a number of reconfigurable struts or arm members extending between a distal collar and proximal collar; however, this is intended only to be illustrative and suitable basket anchors are not intended to be limited to baskets only having struts or arms, as will be described in further detail below. Examples of suitable anchors are further described in detail in the references which have been incorporated by reference above as well as in U.S. Pat. App. Serial No. 10/612,170 filed July 1, 2003, which is also incorporated herein by reference in its entirety.

[0067] As mentioned above, the anchor preferably exerts a force sufficient to maintain or secure a tissue plication yet still allows for adequate blood flow to occur within the tissue underlying the anchor. When the anchor has been configured into its expanded configuration, a load or force may be applied to the anchor until the anchor has been optimally configured to accommodate a range of deflections while the anchor itself

maintains or exerts a substantially constant force against the tissue. Anchor deflection may occur, e.g., when the proximal and distal collars of an anchor have been advanced or urged towards one another such that the arms or struts extending therebetween are at least partially deflected. Moreover, anchor deflection may be due to various movements of the tissue attributable to, e.g., peristalsis, patient movement, weight of the gastrointestinal organ itself, etc.

[0068] Figs. 3A, 4A, and 5A illustrate an example of how the progressive deflection of an anchor may result in a substantially constant force exerted by the anchor itself. As shown in the graph **70** of Fig. 3A, an amount of anchor deflection, **x**, is plotted against the resulting force, **F**, exerted by the anchor. Fig. 3B shows an illustrative profile of an exemplary anchor; proximal collar **14**, distal collar **16**, and struts **12** are shown for reference. With proximal collar **14** stationary relative to the anchor, distal collar **16** may be urged initially at some distance, **x**. The anchor may thus be configured into an initial deflected configuration **72**, as shown in Fig. 3B. The deflection may be induced via a suture or flexible member urging the collars towards one another, e.g., during tissue plication formation or securement.

[0069] Fig. 3A shows the corresponding increase in force **78** over the initial loading of the anchor through deflection, **x**. As the deflection of the anchor is increased, the anchor may be configured into a configuration **72'**, as shown in Fig. 4B, where the increasing force exerted by the anchor passes an inflection point **74** and enters an "optimal" window or range **80** in which the exerted force remains relatively constant over a range of deflections, as shown by the loading graph **70'** in Fig. 4A. Within this range **80** of deflections, the amount of force exerted by the anchor may be substantially constant, i.e., relatively constant or increasing at a rate lower than the rate of initial loading **78** or rate of "over" loading **82** the anchor, as shown below.

[0070] At the upper portion of range **80**, the force exerted by the anchor may begin to increase relative to the deflection, as indicated by loading curve **82** beyond inflection point **76** shown in the loading graph **70"** of Fig. 5A. Fig. 5B shows the corresponding over-loaded anchor configuration **72"** where the anchor may be seen as having been deflected beyond the configuration shown in Fig. 4B. The force representing the over loading of the anchor may increase steadily until the anchor is forced into a configuration

where proximal **14** and distal **16** collars have been urged towards one another to the point where they contact one another.

[0071] Knowing the anchor deflection-to-exerted force characteristics for a given anchor, one may load an anchor with a tension or compression force such that subsequent deflections of the underlying tissue being anchored occur within specified ranges, such as the optimal range. For instance, an anchor may be pre-loaded such that tissue fluctuations or movements occur within the optimal window or range where the force exerted by the anchor remains relatively constant over a range of deflections. This in turn may ensure that the underlying tissue is not subject to over-compression by the anchors.

[0072] One method for limiting the loading or pre-load force upon an anchor may involve including a post or stop **98** in the anchor body, as shown in the anchor variation **90** of Fig. 6A, which shows a partial cross-sectional view of the anchor. Post or stop **98** may be integrally formed with proximal collar **94** and extend distally between struts **92**. Alternatively, post **98** may also be fabricated separately and attached through one of a number of mechanical methods to proximal collar **94**, e.g., adhesives, threading, interference fitted, etc. Post **98** may define a lumen to allow suture **38** to pass through the anchor **90**. The anchor **90** may be loaded via suture **38** until the anchor **90** is configured to fall within the optimal window or range. As the underlying tissue moves, the anchor may be deflected accordingly; however, if the anchor is subjected to large deflections by the tissue, post **98** may prevent distal collar **96** of the anchor from over-compressing the anchor, as shown in the compressed configuration **90'** of Fig. 6B.

[0073] Another variation which may be utilized to limit the loading of the anchor during anchor placement and tensioning against the tissue is shown in the partial cross-sectional views of Figs. 7A and 7B. Tensioning assembly **100** may be seen proximally of anchor proximal collar **14** contained within the delivery push tube or catheter **102**. An elongate member **104**, e.g., a tubular member, may extend through catheter **102** and define a specified region **108** having a known coefficient of friction near or at the distal end of elongate member **104**. Frictional region **108** may be an area of the elongate member **104** having a separate material of known frictional coefficient coated or adhered thereon. Alternatively, the frictional region **108** may be integral with elongate member **104** and may simply be abraded or roughened to alter the frictional coefficient of region **108**.

[0074] Suture **38** may be attached at attachment point **106** to the distal end of elongate member **104** and may further extend into the anchor. As elongate member **104** is slid proximally through catheter **102** to impart a tension or load upon the anchor via suture **38**, member **104** may pass through at least one or more regions which are in intimate contact around member **104**. The regions in contact with member **104** may comprise at least a first frictional area **110** having a known first frictional coefficient. As elongate member **104** is withdrawn proximally in the direction of travel **118**, frictional region **108** may slide against first frictional area **110** and generate a first frictional force **I**, as indicated by plot **120** on the graph of Fig. 8A. The generated first frictional force **I** may be detected through any number of various devices and may be used to indicate to the operator that anchor is being loaded.

[0075] As elongate member **104** is withdrawn further proximally, frictional region **108** may be withdrawn proximally of first frictional area **110** and against second frictional area **112**, which may also have a known second frictional coefficient different from the first frictional coefficient of the first frictional area **110**, as shown in Fig. 7B. A length of first frictional area **110** may accordingly be configured to correspond to the length of suture needed to load the anchor into its optimal configuration. As elongate member **104** slides against second frictional area **112**, a second frictional force **II** may be generated which may be less than the first frictional force. Fig. 8B shows the drop in the generated frictional force as indicated by plot **122**. This change in the detected force may thus be utilized to indicate to the operator that anchor has been configured within an optimal range of deflections. Once the anchor has been optimally configured, the suture may be secured relative to the anchor using any number of the cinching and/or locking methods as described in U.S. Pat. App. Serial Nos. 10/840, 950 filed 05/07/2004 (Attorney Docket No. 021496-000900 US); 10/841,245 filed 05/07/2004 (Attorney Docket No. 021496-001000 US); 10/840,951, filed 05/07/2004 (Attorney Docket No. 021496-001100 US); and 10/841, 411 filed 05/07/2004 (Attorney Docket No. 021496-001200 US), which have been incorporated by reference above.

[0076] To prevent elongate member **104** from being over-withdrawn proximally and from over-compressing the anchor, protrusions **114** may project from elongate member **104** and corresponding stops **116** may project from within catheter **102**. Protrusions **114** and the corresponding stops **116** may accordingly be configured to prevent the further withdrawal of elongate member **104** from catheter **102**. Moreover, although first **110** and

second **112** frictional areas are shown in this example, a single frictional area or additional areas may be utilized, each having a different coefficient of friction. Furthermore, first **110** and second **112** frictional areas may be fabricated from different materials or they may be made from the same or similar material as catheter **102** and simply coated or covered with the various materials. For instance, first frictional area **110** may be fabricated from a material such as PEBAX®, while second frictional area **112** may be fabricated from a material such as HDPE. Alternatively, rather than utilizing a coating or covering, first **110** and second **112** frictional areas may be textured or abraded to create surfaces having differing frictional coefficients. The types of materials utilized or the types of surface textures created or even the number of different frictional areas are not intended to be limiting but are merely presented as possible variations. So long as a detectable change in the generated frictional force between elongate member **104** and the surrounding frictional region is created, any number of materials or regions may be utilized.

[0077] Fig. 9 shows another anchor tensioning variation in assembly **130**. As shown, the tensioning assembly may be contained within delivery push tube or catheter **132**. An elongate pull member **134**, which may be manipulated via its proximal end by the user, may be connected to a tensioning block or member **136** via spring member **138**. Pull member **134** and tensioning block or member **136** may generally be formed from a variety of biocompatible metals, e.g., stainless steel, Nitinol, etc., or plastics provided that the material is rigid relative to spring member **138** and suture **140** and will not affect the measurement of the linear deformation of spring member **138**. Spring member **138** may generally comprise a linear spring element having a known spring constant. Suture **140** may be attached to a distal end of block **136** and further routed into or through distally located the tissue anchor.

[0078] During use in loading the tissue anchor, pull member **134** may be withdrawn proximally by its proximal end. As it is withdrawn, the force required to withdraw member **134** may be measured. With the spring constant and the measured force, the amount of linear deflection may be calculated to determine the amount of deflection the anchor has undergone. Alternatively, suture **140** may be marked uniformly at known distances with markings or gradations **142**. As the pull member **134** is withdrawn, the length of suture **140** withdrawn into catheter **132** may be measured visually using, e.g., a video endoscope, by counting the number of gradations **142** passing into catheter **132**.

Knowing the linear distance and the spring constant, the anchor deflection may be calculated. Thus, measurement of either the force required to withdraw member **134** or the linear distance traveled by suture **140** may be utilized to determine the anchor deflection. With the known deflection, the assembly may be configured to indicate when the anchor has been deflected to a predetermined level, e.g., when the anchor has been deflected within the optimal range.

[0079] Another alternative of an anchor tensioning assembly is shown in the partial cross-sectional view of Fig. 10. Assembly **150** may generally comprise an elongate pull member **152** connected to tensioning block or member **154**. Pull member **152** and tensioning block **154** may be fabricated from the same or similar materials as described above. A third element **156** having a known length which is less rigid than pull member **152** or tensioning block **154** may connect the two. This element **156** may have strain gauge **158** attached thereto for measuring the strain of the element **156** as pull member **152** is withdrawn proximally. The signals detected from the strain gauge **158** may be transmitted via wires **160** to a processor and/or display **162** located externally of the patient to record and process the strain information. With the known original length of element **156** and the measured strain, the length of linear deflection of the attached anchor may be calculated. With this information, the anchor deflection may be determined and the assembly **150** may be configured to indicate when the anchor has been deflected to a predetermined level to ensure optimal loading of the anchor.

[0080] Yet another alternative is shown in the partial cross-sectional view of Fig. 11. In this variation, assembly **170** may simply comprise an anchor having a stepped proximal collar **172** to define a step or detent **174** which prevents the passage of stop member **176** contained within the anchor. The length of suture **38** extending from stop member **176** to the attachment point within the anchor may be of a predetermined length such that when stop member **176** is seated against proximal collar **172**, the suture length may compress the anchor into a predetermined deflection level. This deflection level may be preset to configure the anchor to any desired configuration, as described above.

[0081] Yet another variation is shown in the partial cross-sectional views of Figs. 12A and 12B. Assembly **180** may generally comprise elongate pull member **152** and tensioning block or member **154**, as above. However, a fuse material **182**, i.e., a length of material having a preset or known failure or break strength, may be used to join pull

member **152** and tensioning block **154**. This fuse **182** may generally comprise a variety of materials, e.g., silk, stainless steel, etc., provided that the failure strength of fuse **182** is less than the force necessary for causing necrosis of the tissue to be anchored. For instance, a fuse **182** may be configured to break at a pressure of, e.g., 2 psi.

[0082] In operation, as elongate pull member **152** is withdrawn proximally, tensioning block **154** may be withdrawn as it is pulled by fuse **182**. As the anchor becomes compressed and the force on fuse **182** increases, once the force reaches the pre-set limit, the fuse **182** may break, as shown in Fig. 12B, thereby preventing further compression of the anchor and limiting the force applied onto the tissue.

[0083] Fuse **182** may be comprised from various materials. Optionally, the fuse may be altered to modify its break strength, e.g., by including multiple notches **192**, **194**, as seen in fuse variation **190** of Fig. 13A to create a necked-down region. Alternatively, a single notch **198** may be utilized, as seen in fuse variation **196**. The notches may be defined on the fuse to alter the break strength or to ensure the breakage or failure of the fuse.

[0084] When tensioning the anchors using any of the devices or methods described herein, various mechanisms may be used to apply the tensioning force on the suture. One mechanism is shown in the partial cross-sectional view of Fig. 14A, which shows a tensioning assembly **200** positioned within catheter **132**. The assembly may generally comprise tensioning mechanism **202**, which may have an anchor interface member **206** and a tensioning interface member **208** configured to slide relative to one another within catheter **132**. Anchor interface member **206** may define anchor collar channel **204** configured to receive and temporarily hold the proximal collar **14** of an anchor to be loaded.

[0085] Tensioning interface member **208** may be configured to slide relative to anchor interface member **206** via a slidable connection **210**. Tensioning member **208** may also comprise suture coupler **212** and hook **214** for holding terminal end **216** of suture **38** during a tensioning procedure. Tensioning member **208** and anchor member **206** may be urged towards one another via some biased member, e.g., spring member **218**, having a known spring constant. In use, when a tissue anchor is ready to be loaded, the proximal collar **14** may be held within anchor collar channel **204** and with terminal end **216** of suture **38** retained by hook **214**, tensioning member **208** may be withdrawn

proximally relative to anchor member **206** until the desired tensioning level is reached. Other variations utilizing, e.g., a strain gauge, for measuring the tension applied or utilizing, e.g, graspers, rather than a hook may be utilized to desirably tension the tissue anchors.

[0086] Fig. 14B shows a perspective view of an alternative tensioning assembly **201** which may be used to apply the load upon the anchor. This assembly **201** may be utilized in conjunction with any of the tension measuring apparatus described herein. As shown, anchor **10'** may be positioned at the distal end of base **205** with suture **38** extending proximally while being tensioned via suture coupler **212**, as in assembly **200** described above. Graspers **203**, which may be articulated to open or close, may be used to hold suture terminal end **216** while tensioning anchor **10'**. Base **205** may be configured to extend longitudinally, as above, or suture coupler **212** may be configured to slide proximally to tension the anchor **10'**.

[0087] Fig. 14C shows a device which may be used by the surgeon or operator outside a patient body to tension the anchors positioned within the body. Generally, the handle assembly may comprise handle **211** and a hollow elongate shaft **215** extending from the handle **211**. Shaft **215** may function much like a laparoscopic shaft if shaft **215** is rigid; alternatively, shaft **215** may be configured to be flexible for advancement within or through an endoscope or other working lumen, if so desired. A tensioning assembly, as described above, may be positioned within the lumen of shaft **215** near or at the distal end of shaft **215** and the control mechanisms, e.g., suture coupler **212**, may be actuatable from handle **211**. In one variation, control wheel or ratchet control **213**, which may be located on handle **211**, may be rotated in the direction of arrow **217** to actuate base **205** or suture coupler **212** in a proximal direction, as indicated by arrow **219**. Tensioning suture **38** with ratchet control **217** may draw anchors **207**, **209** towards one another to secure tissue fold **F** while also applying an appropriate load upon anchors **207**, **209**.

[0088] Various other factors of the tissue anchors may be modified to affect the tensioning and loading characteristics when deflecting the anchors. Moreover, some of the factors may also affect the interaction of the anchor with respect to the tissue in ensuring that the tissue is not over-compressed and that adequate blood flow may occur within the tissue directly beneath the anchor.

[0089] One factor may include varying the number of arms or struts of the anchor. For instance, the anchor may be configured to have, e.g., seven struts or arms **12** which deflect about the proximal **14** and distal **16** collars, as shown in the flattened view of one anchor variation **220** in Fig. 15A. Fig. 15B shows a side view of the flattened anchor **220** while Fig. 15C shows a perspective view of the anchor **220** in an unexpanded delivery configuration.

[0090] Fig. 16A shows another variation of anchor **230** in a flattened view with struts or arms **232** extending between proximal collar **236** and distal collar **238**. In this variation, five arms **232** may be utilized to increase the spacing **234** defined between adjacent arms **232**. The increased spacing **234** may be utilized to ensure the blood flow in the tissue beneath the tissue. Fig. 16B shows a side view of the flattened anchor **230** and Fig. 16C shows a perspective view of anchor **230** in its unexpanded delivery configuration. Other variations are discussed below.

[0091] Aside from varying the number of struts or arms, the configuration of the arms themselves may be varied. As seen in Fig. 16A, cross-sections of an individual arm **232** may be viewed for discussion purposes at three sections, proximal **I**, middle **II**, and distal **III** portions of the arm **232**. Figs. 17A to 17J show examples of possible variations for cross-sectional areas of an arm at each section, proximal **I**, middle **II**, and distal **III**. These figures are not intended to be limiting but are merely intended as examples of possible arm configurations.

[0092] Fig. 17A shows an arm configuration where sections **I** and **III** may be square in shape with the middle section **II** rectangular.

[0093] Fig. 17B shows an arm configuration where sections **I** and **III** may be rectangular in shape with the middle section **II** square.

[0094] Fig. 17C shows an arm configuration where sections **I** and **III** may be rectangular in shape in a transverse direction with the middle section **II** square.

[0095] Fig. 17D shows an arm configuration where sections **I** and **III** may be square in shape with the middle section **II** rectangular in a traverse direction.

[0096] Fig. 17E shows an arm configuration where all sections **I**, **II**, and **III** may be square in shape.

[0097] Fig. 17F shows an arm configuration where all sections **I**, **II**, and **III** may be rectangular in shape.

[0098] Fig. 17G shows an arm configuration where sections **I** and **III** may be circular in shape with the middle section **II** rectangular.

[0099] Fig. 17H shows an arm configuration where sections **I** and **III** may be elliptical in shape with the middle section **II** circular.

[0100] Fig. 17I shows an arm configuration where sections **I** and **III** may be circular in shape with the middle section **II** elliptical.

[0101] Fig. 17J shows an arm configuration where all sections **I**, **II**, and **III** may be circular in shape.

[0102] As mentioned above, varying the number of struts or arms may be utilized to vary not only the contact area with respect to the underlying tissue, but to also affect the optimal loading characteristics of the anchor. Aside from the number of arms, the positioning of the arms may also be utilized. For example, Figs. 18A to 18F show end views of anchor variations having a number of varying arms and arm positions. Again, these figures are not intended to be limiting but are merely intended as examples.

[0103] Fig. 18A shows the end view of an anchor **240** having 3 arms uniformly spaced apart.

[0104] Fig. 18B shows the end view of an anchor **242** having 4 arms uniformly spaced apart.

[0105] Fig. 18C shows the end view of an anchor **244** having 5 arms uniformly spaced apart.

[0106] Fig. 18D shows the end view of an anchor **246** having 6 arms uniformly spaced apart.

[0107] Fig. 18E shows the end view of an anchor **248** having 7 arms uniformly spaced apart.

[0108] Fig. 18F shows the end view of an anchor **250** having 9 arms uniformly spaced apart.

[0109] Any number of arms may be utilized as practicable and although the arms in the above examples are uniformly spaced apart from one another, the spacing between the arms may be varied irregularly or arbitrarily provided that the spacing between the arms enable adequate blood flow in the underlying tissue.

[0110] Not only can the number of arms and spacing between the arms be varied, but also the arm configurations themselves. For instance, the arms may be pre-formed into various shapes depending upon the desired effects on the anchor loading characteristics. As above, these figures are not intended to be limiting but are merely intended as examples.

[0111] Fig. 19A shows an illustrative side view of anchor **260** having curved arms.

[0112] Fig. 19B shows an illustrative side view of anchor **262** having circularly-shaped arms.

[0113] Fig. 19C shows an illustrative side view of anchor **264** having elliptically-shaped arms.

[0114] Fig. 19D shows an illustrative side view of anchor **266** having bow-shaped arms.

[0115] Fig. 19E shows an illustrative side view of anchor **268** having arms shaped into a figure-eight manner.

[0116] Fig. 19F shows an illustrative side view of anchor **270** having minimally-radiused arms.

[0117] Aside from the arm shapes, the length of the collars may be varied as well. Fig. 20A shows anchor variation **280** having extended anchor collars **282**, which may act to reduce the radius of the arms. Fig. 20B shows anchor variation **284** having reduced collars **286**, which may act to increase the radius of the arms. As above, these figures are not intended to be limiting but are merely intended as examples.

[0118] When the anchors are deployed into or against the tissue, at least one portion of the anchor arms are generally against the tissue surface while another portion of the arms are exposed within the lumen. The exposed portions of the anchor may be optionally coated or covered with a material to protect against exposure to foreign materials, e.g., food or other object which may be ingested by the patient, other surgical

tools, etc. Accordingly, as shown in the perspective view of anchor variation **290** in Fig. 21A, biocompatible coating or covering **292** may be placed over the entire length of the anchor arms **12** or only along the portions of the arms **12** not against the tissue. The coating or covering **292** may be comprised from various materials, e.g., elastomers, plastics, etc.

[0119] Alternatively, a mesh or skirt-like covering **298** may be placed over the exposed portion of the anchor **294**, as shown in Fig. 21B, which is attached to the anchor via attachment points **298** along each of some of the arms **12**. Yet another alternative may be seen in anchor variation **300** in Fig. 21C in which the entire anchor itself may be covered with a distensible or expandable covering or mesh.

[0120] Although a number of illustrative variations are described above, it will be apparent to those skilled in the art that various changes and modifications may be made thereto without departing from the scope of the invention. Any of the modifications to an anchor, e.g., number of arms, arm configuration, cross-sectional variations, anchor collar length, coatings or coverings over the anchor, etc., may be done in a variety of combinations with one another. For instance, depending upon the desired loading characteristics, an anchor may be made having a number of arms with various cross-sectional areas along one or more of the arm lengths and may additionally have one or both collars varied in length.

[0121] Any of the combinations or modifications is intended to be within the scope of this invention. Moreover, although configurations may be shown with various types of anchors, it is intended that the various configurations be utilized in various combinations as practicable. It is intended in the appended claims to cover all such changes and modifications that fall within the true spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A system for loading an anchor for placement against a tissue surface, comprising:

an anchor body having a delivery configuration and an expanded configuration adapted for placement against the tissue surface; and

a loading mechanism in communication with the anchor body, wherein the loading mechanism is adapted to indicate a loading condition upon the anchor body.

2. The system of claim 1 further comprising a length of suture extending between the anchor body and the loading mechanism.

3. The system of claim 2 further comprising a locking mechanism adapted to pass the anchor body in a first direction relative to the length of suture upon application of a cinching force.

4. The system of claim 3 wherein the locking mechanism is further adapted to impart a locking force upon the length of suture when the anchor body is urged in a second direction opposite to the first direction, and wherein the locking force is greater than the cinching force.

5. The system of claim 1 wherein the anchor body is adapted to be delivered through a hollow member for placement against the tissue surface.

6. The system of claim 5 wherein the hollow member comprises a needle.

7. The system of claim 1 wherein the anchor body comprises a basket-type anchor.

8. The system of claim 1 wherein the anchor body comprises a plurality of reversibly deformable arms extending between a proximal collar and a distal collar.

9. The system of claim 8 wherein each of the deformable arms are adapted to contact the tissue surface.

10. The system of claim 1 wherein the anchor body comprises a plurality of deformable arms which are configured to define a space between adjacent arms for minimizing contact between the anchor body and the tissue surface.

11. The system of claim 1 wherein the anchor body is comprised of a shape memory or superelastic alloy.

12. The system of claim 1 wherein the anchor body is comprised of nitinol.

13. The system of claim 1 wherein the loading condition is indicative of a deformation state of the anchor body.

14. The system of claim 1 wherein the loading mechanism is further adapted to indicate a predetermined loading condition upon the anchor body.

15. The system of claim 14 wherein the predetermined loading condition is indicative of a deformation range where the anchor body exerts a substantially constant force upon the tissue surface.

16. The system of claim 1 wherein the loading mechanism comprises a post extending from the anchor body, the post being configured to inhibit deformation of the anchor body beyond a predetermined limit.

17. The system of claim 1 wherein the loading mechanism comprises:

a first member defining a first region with a first frictional coefficient;

a second member defining at least a second region with a second frictional coefficient different from the first frictional coefficient,

wherein the first member and the second member are adapted to slide relative to one another such that a first frictional force is generated by contact between the first region and the second region, and

wherein a change in the first frictional force is indicative of a predetermined loading condition upon the anchor body.

18. The system of claim 17 wherein the second member further defines a third region with a third frictional coefficient different from the second frictional coefficient.

19. The system of claim 17 wherein the first member comprises an elongate tubular member.

20. The system of claim 17 wherein the second member comprises an outer member circumferentially disposed over the first member.

21. The system of claim 17 wherein the first member or the second member further comprises a stop adapted to limit a longitudinal motion between the respective members.

22. The system of claim 1 wherein the loading mechanism comprises a spring member having a predetermined spring coefficient.

23. The system of claim 1 wherein the loading mechanism comprises a strain gauge adapted to measure a longitudinal deformation of a tensioned region, the deformation being indicative of the loading condition upon the anchor body.

24. The system of claim 23 further comprising a monitor in communication with the strain gauge, the monitor being adapted to indicate a predetermined loading condition upon the anchor.

25. The system of claim 1 wherein the loading mechanism comprises a stop located upon the anchor body, the stop being configured to inhibit deformation of the anchor body beyond a predetermined limit.

26. The system of claim 1 wherein the loading mechanism comprises a fuse member adapted to break when a predetermined loading condition is reached, thereby inhibiting deformation of the anchor body beyond a predetermined loading condition.

27. The system of claim 26 wherein the fuse member comprises a length of material having a known failure strength.

28. The system of claim 26 wherein the fuse member comprises a notched material.

29. The system of claim 1 further comprising a covering or coating disposed at least partially over the anchor body.

30. A method for loading an anchor for placement against a tissue surface, comprising:

positioning the anchor relative to the tissue surface;

applying a load to the anchor such that the anchor is configured into a partially compressed state against the tissue surface; and

adjusting the load such that the anchor exerts a substantially constant force upon the tissue surface.

31. The method of claim 30 wherein positioning the anchor comprises deploying the anchor via a hollow needle against the tissue surface.

32. The method of claim 30 wherein positioning the anchor comprises configuring the anchor from a delivery configuration to an expanded configuration.

33. The method of claim 30 wherein positioning the anchor comprises deploying a plurality of deformable arms against the tissue surface such that a space is defined between adjacent arms for minimizing contact between the anchor and the tissue surface.

34. The method of claim 30 wherein applying a load to the anchor comprises applying the load to a length of suture.

35. The method of claim 34 further comprising imparting a locking force upon the length of suture such that the locking force inhibits the anchor from relaxing from its compressed state.

36. The method of claim 30 wherein adjusting the load comprises applying a predetermined loading condition upon the anchor.

37. The method of claim 30 wherein adjusting the load comprises applying the load until the anchor exerts the substantially constant force upon the tissue surface over a range of deflection of the anchor.

38. The method of claim 30 wherein adjusting the load comprises applying the load until a change in the load is detected.

39. The method of claim 30 wherein adjusting the load comprises detecting the substantially constant force via a spring member having a predetermined spring coefficient.

40. The method of claim 30 wherein adjusting the load comprises detecting the substantially constant force via a strain gauge adapted to measure a longitudinal deformation of a tensioned region.

41. The method of claim 30 wherein adjusting the load comprises detecting the substantially constant force via a fuse member adapted to break when the constant force is reached.

42. An anchor adapted to exert a substantially constant force against a tissue surface, comprising:

a proximal collar;

a distal collar;

a plurality of deformable arms each extending between the proximal and distal collars,

wherein the anchor is adapted to self-configure from a delivery configuration to an expanded configuration for placement against the tissue surface, and

wherein the anchor is further adapted to exert a substantially constant force against the tissue surface over a range of deflections when the proximal and distal collars are moved relative to one another.

43. The anchor of claim 42 wherein the proximal collar defines a lumen therethrough.

44. The anchor of claim 42 wherein the distal collar defines a lumen therethrough.

45. The anchor of claim 42 wherein the anchor is comprised of a shape memory or superelastic alloy.

46. The anchor of claim 42 wherein the anchor is comprised of nitinol.

47. The anchor of claim 42 wherein the plurality of deformable arms define a space between adjacent arms for contact against the tissue surface.

48. The anchor of claim 42 wherein the deformable arms are parallel.

49. The anchor of claim 42 wherein the deformable arms each define a non-uniform cross-section along a length of the arm.

50. The anchor of claim 49 wherein each of the arms is tapered along its length.

51. The anchor of claim 42 wherein each of the arms define at least a proximal section, a distal section, and a middle section.

52. The anchor of claim 51 wherein the proximal and distal sections have uniform cross-sections.

53. The anchor of claim 42 wherein the arms number at least two.

54. The anchor of claim 42 wherein the arms each defines a profile when in the expanded configuration, the profile selected from the group consisting of curves, semi-circles, semi-ellipses, figure-eights, U-shapes, and combinations thereof.

55. The anchor of claim 42 further comprising a loading mechanism in communication with the anchor, wherein the loading mechanism is adapted to indicate a loading condition upon the anchor.

56. The anchor of claim 42 further comprising a length of suture passing through the anchor.

57. The anchor of claim 56 further comprising a locking mechanism adapted to pass the anchor in a first direction relative to the length of suture.

58. The anchor of claim 57 wherein the locking mechanism is further adapted to impart a locking force upon the length of suture when the anchor is urged in a second direction opposite to the first direction.

59. The anchor of claim 42 wherein the anchor is adapted to be delivered through a hollow member when in the delivery configuration.

60. The anchor of claim 42 further comprising a coating or covering disposed over at least a portion of the anchor.

61. The anchor of claim 60 wherein the coating or covering is disposed over at least a portion of an outer surface of each arm.

62. The anchor of claim 42 further comprising a covering disposed over the anchor.

63. A tissue securement system, comprising:

an anchor having a proximal collar, a distal collar, and a plurality of deformable arms each extending therebetween;

a length of suture disposable through the anchor;

a hollow member adapted to contain the anchor in a delivery configuration,

wherein the anchor is adapted to self-configure from the delivery configuration to an expanded configuration externally of the hollow member, and

wherein the anchor is further adapted to exert a substantially constant force against a tissue surface in the expanded configuration over a range of deflections when the proximal and distal collars are moved relative to one another.

64. The anchor of claim 63 wherein the proximal and distal collars each define a lumen therethrough.

65. The anchor of claim 63 wherein the anchor is comprised of a shape memory or superelastic alloy.

66. The anchor of claim 63 wherein the anchor is comprised of nitinol.

67. The anchor of claim 63 wherein the plurality of deformable arms define a space between adjacent arms for contact against the tissue surface.

68. The anchor of claim 63 wherein the deformable arms are parallel.

69. The anchor of claim 63 wherein the deformable arms each define a non-uniform cross-section along a length of the arm.

70. The anchor of claim 69 wherein each of the arms is tapered along its length.

71. The anchor of claim 63 wherein each of the arms define at least a proximal section, a distal section, and a middle section.

72. The anchor of claim 71 wherein the proximal and distal sections have uniform cross-sections.

73. The anchor of claim 63 wherein the arms number at least two.

74. The anchor of claim 63 wherein the arms each defines a profile when in the expanded configuration, the profile selected from the group consisting of curves, semi-circles, semi-ellipses, figure-eights, U-shapes, and combinations thereof.

75. The anchor of claim 63 further comprising a loading mechanism in communication with the anchor, wherein the loading mechanism is adapted to indicate a loading condition upon the anchor.

76. The anchor of claim 63 further comprising a locking mechanism adapted to pass the anchor in a first direction relative to the length of suture.

77. The anchor of claim 76 wherein the locking mechanism is further adapted to impart a locking force upon the length of suture when the anchor is urged in a second direction opposite to the first direction.

78. The anchor of claim 63 wherein the hollow member comprises a needle.

79. The anchor of claim 63 further comprising a coating or covering disposed over at least a portion of the anchor.

80. The anchor of claim 79 wherein the coating or covering is disposed over at least a portion of an outer surface of each arm.

81. The anchor of claim 63 further comprising a covering disposed over the anchor.

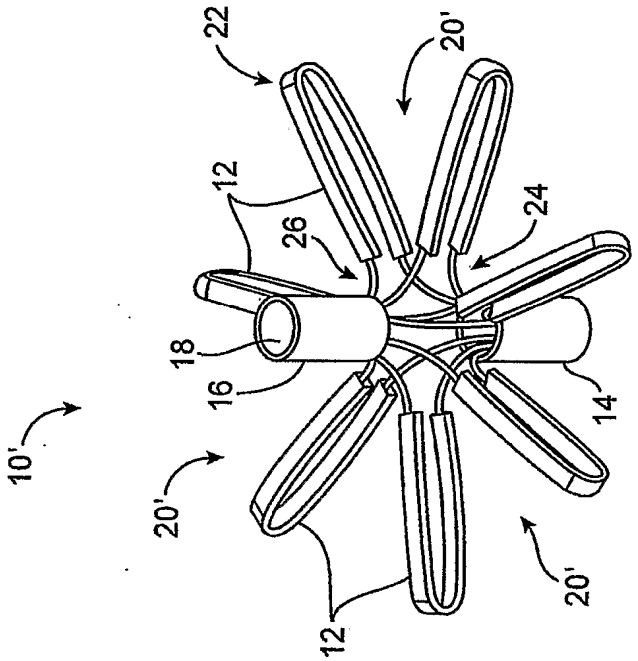


FIG. 1B

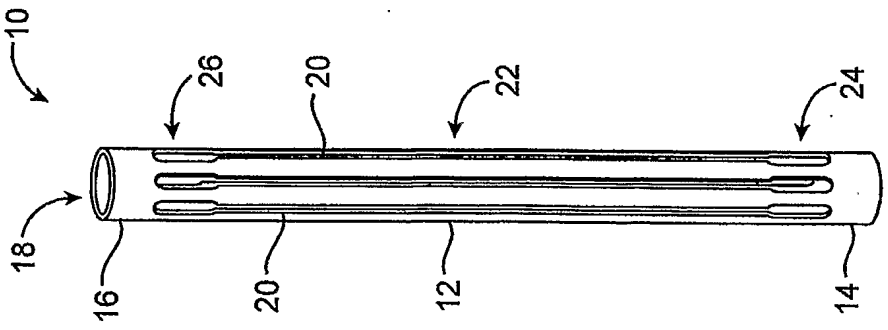
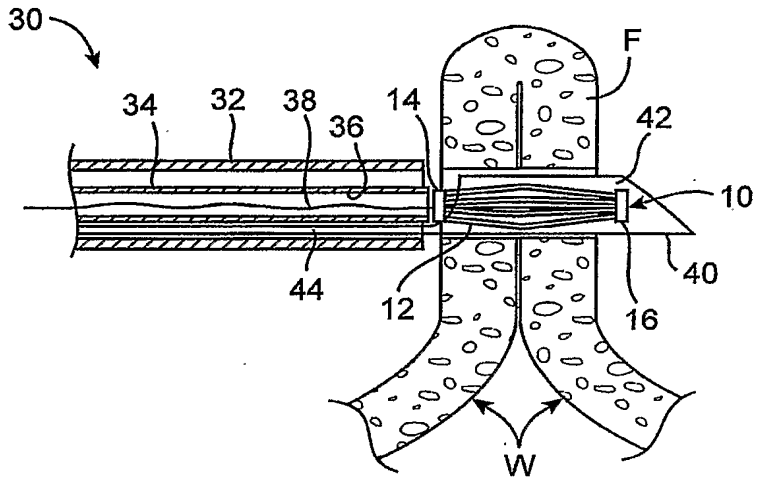


FIG. 1A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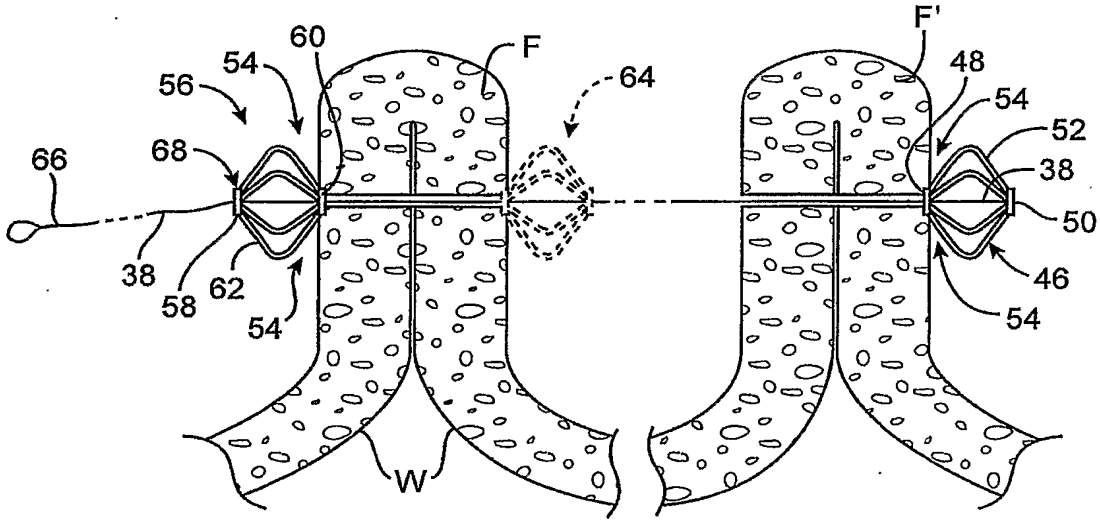
36
14
F
42
10
40
44
12
16
W

FIG. 2A


60
54
56
F
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F'
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54
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46
54
66
68
38
58
62
54
W

FIG. 2B

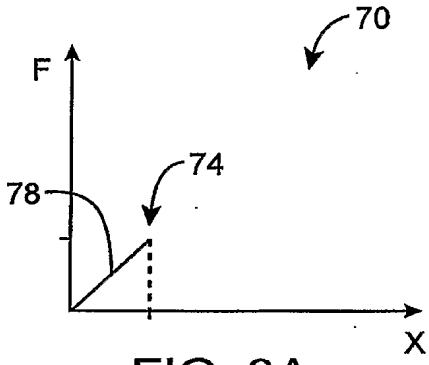

FIG. 3A

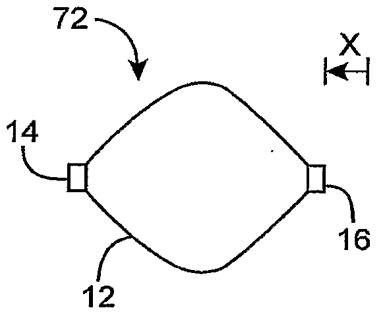

FIG. 3B

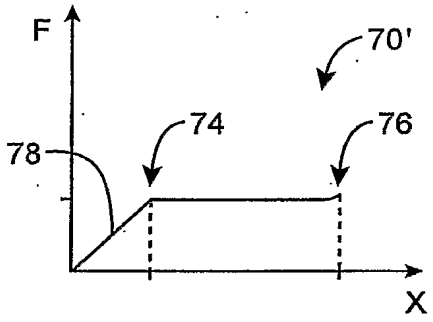

FIG. 4A

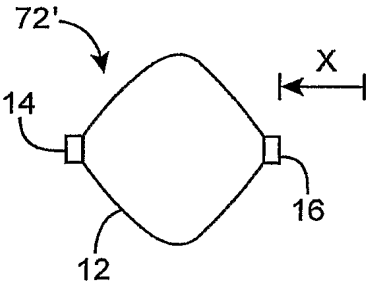

FIG. 4B

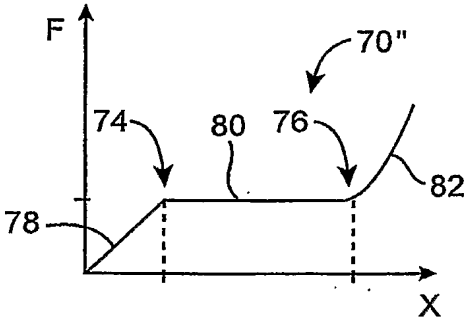

FIG. 5A

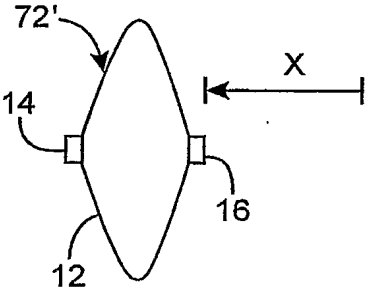

FIG. 5B

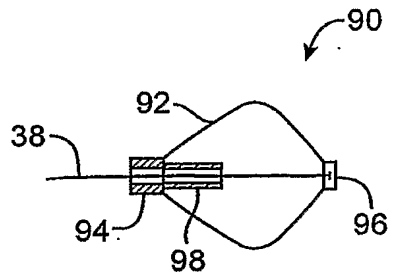

FIG. 6A

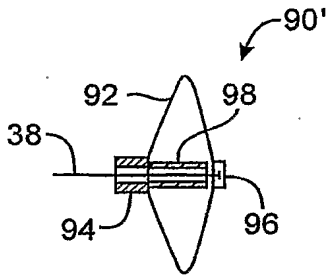

FIG. 6B

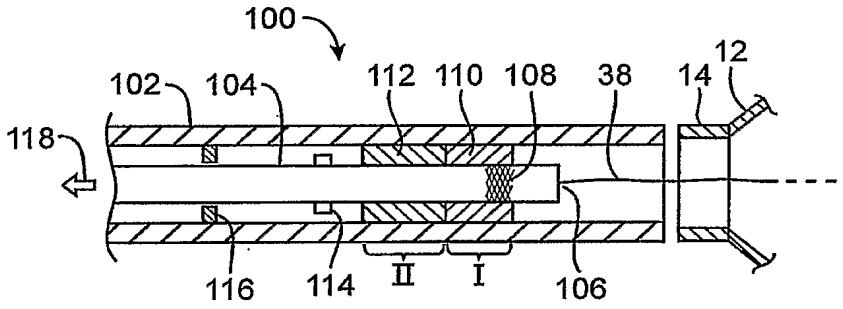

FIG. 7A

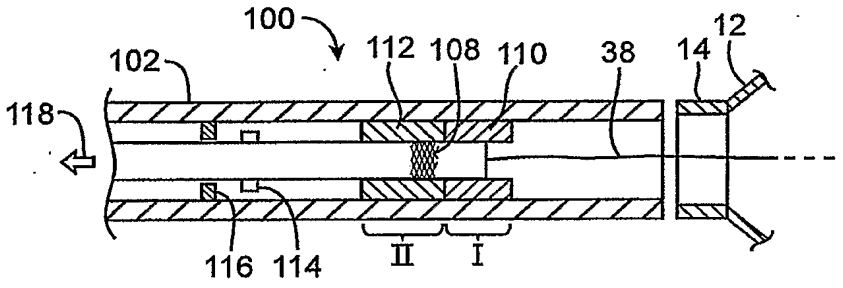

FIG. 7B

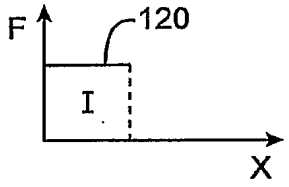

FIG. 8A

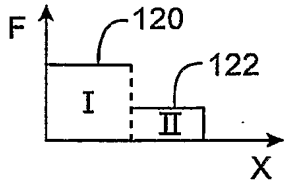

FIG. 8B

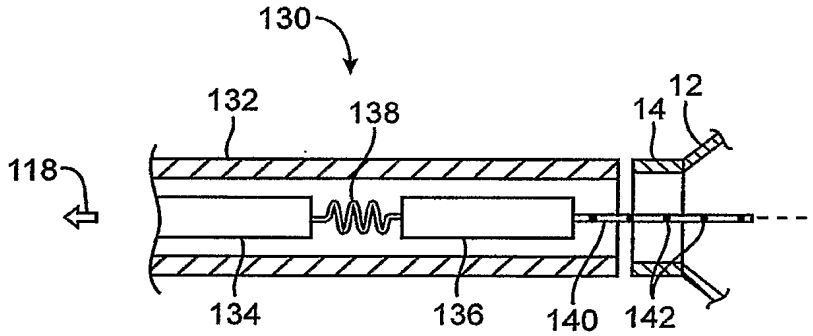

FIG. 9

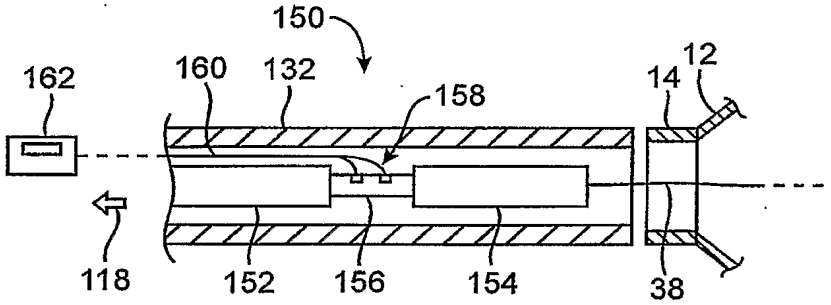

FIG. 10

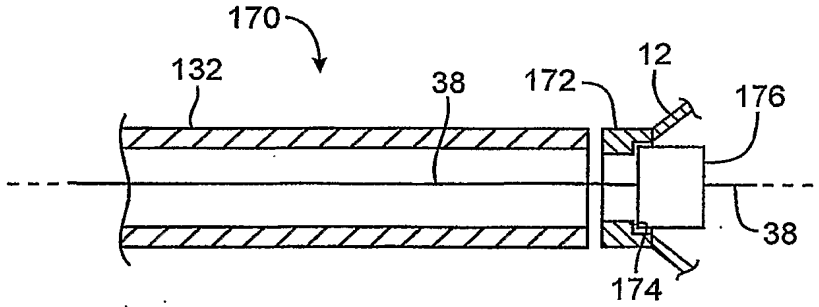

FIG. 11

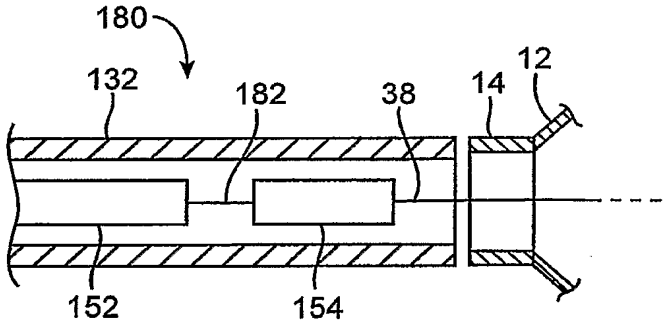

FIG. 12A

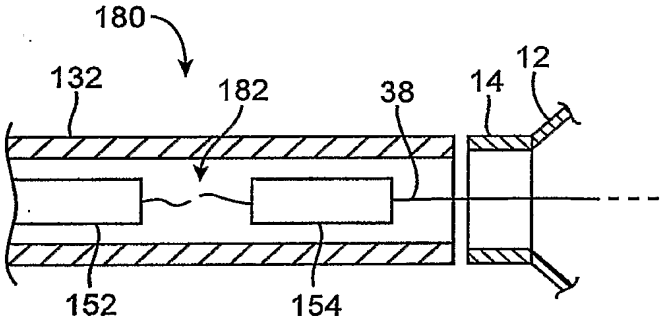

FIG. 12B

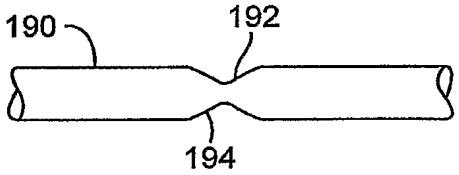

FIG. 13A

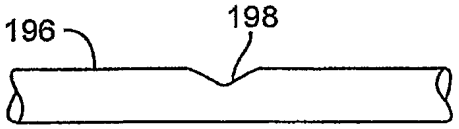

FIG. 13B

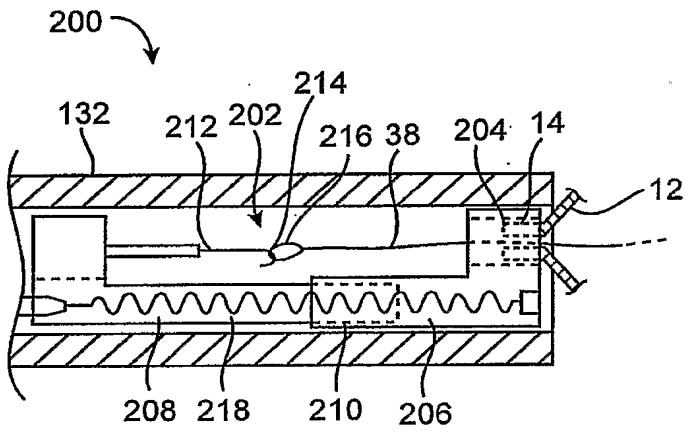

FIG. 14A

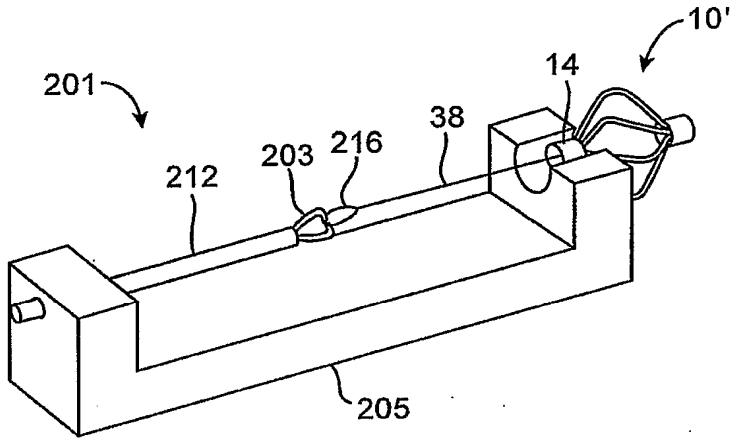

FIG. 14B

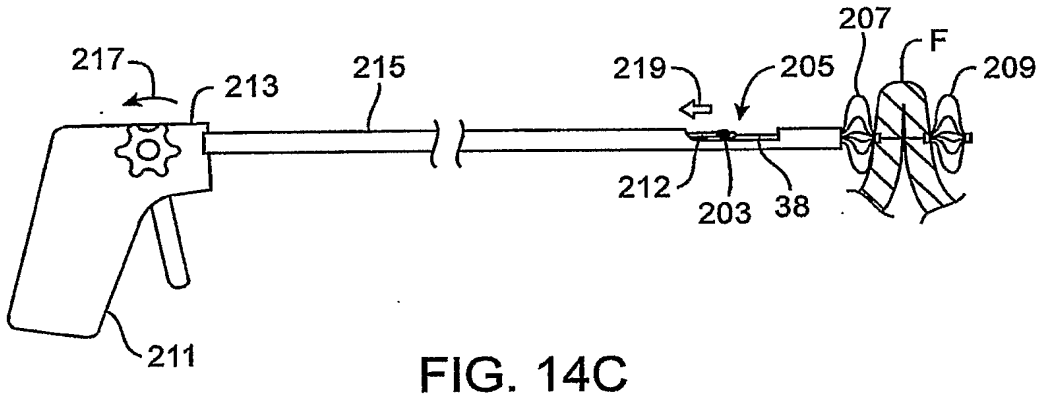

FIG. 14C

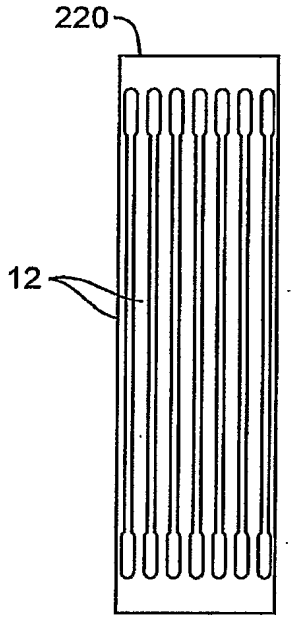

FIG. 15A

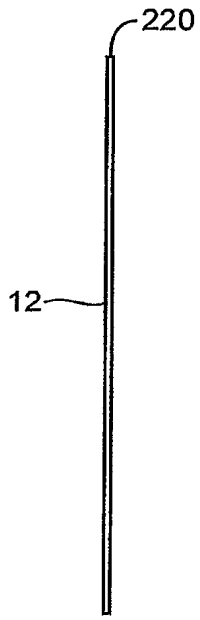

FIG. 15B

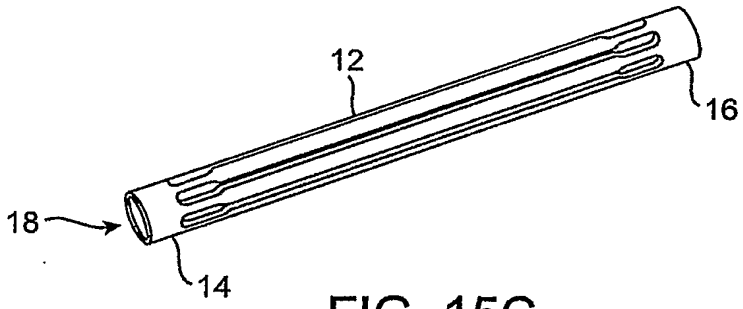

FIG. 15C

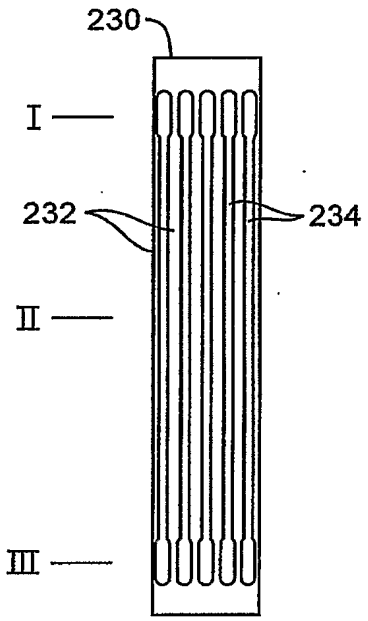

FIG. 16A

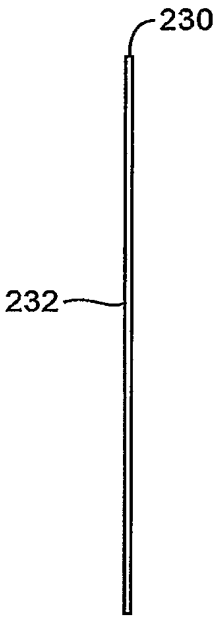

FIG. 16B

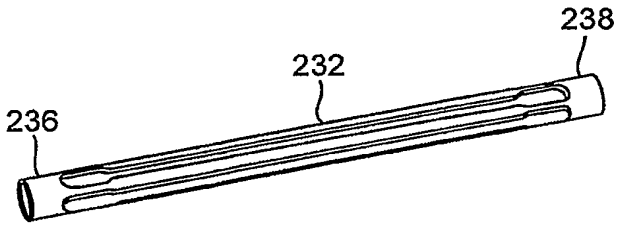

FIG. 16C

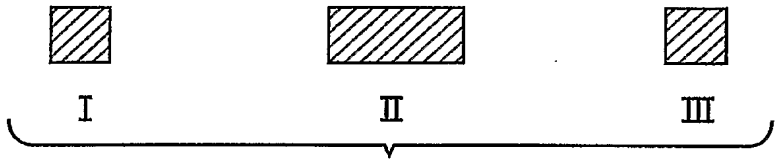

FIG. 17A

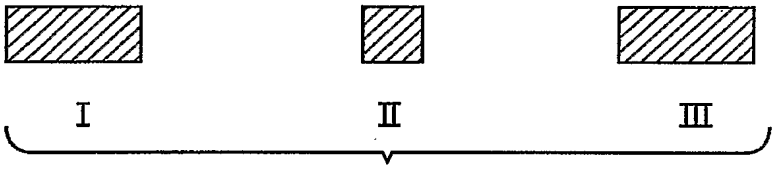

FIG. 17B

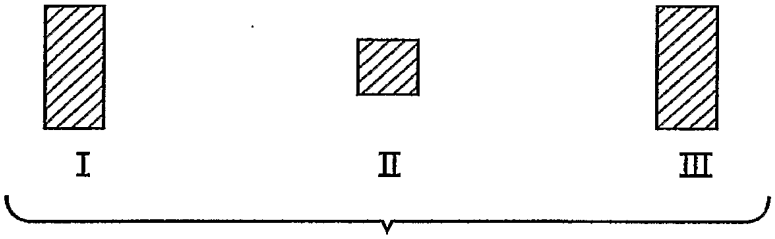

FIG. 17C

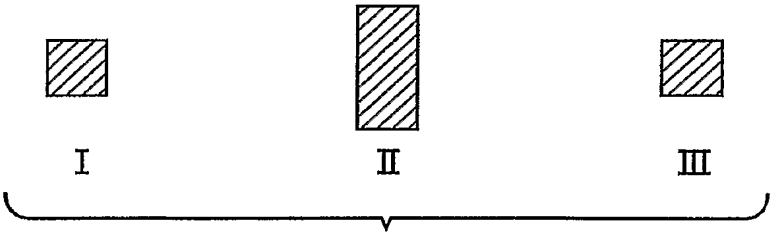

FIG. 17D

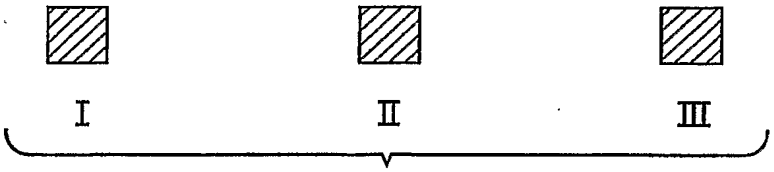

FIG. 17E

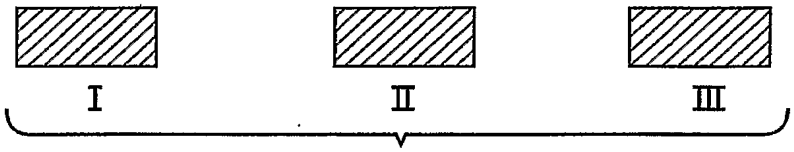

FIG. 17F

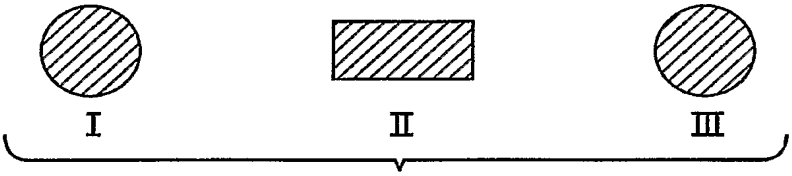

FIG. 17G

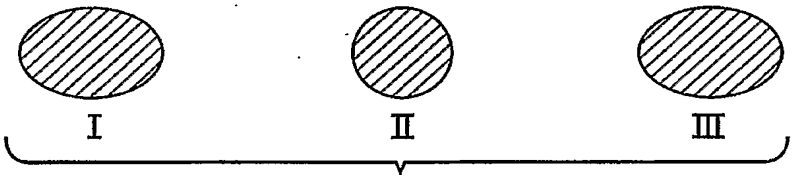

FIG. 17H

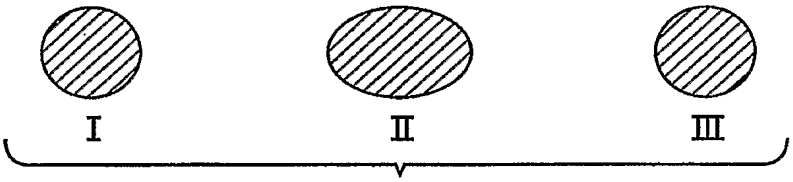

FIG. 17I

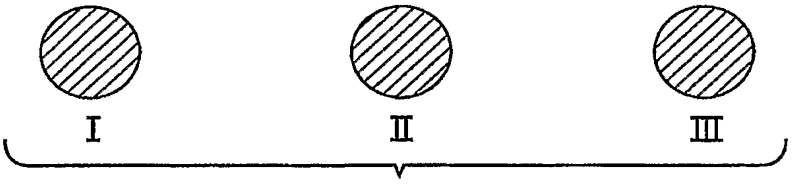

FIG. 17J

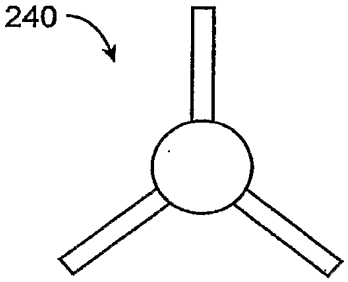

FIG. 18A

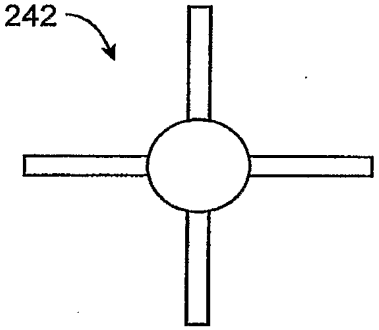

FIG. 18B

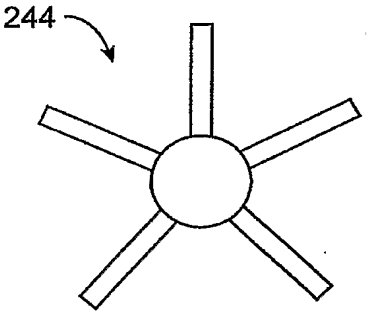

FIG. 18C

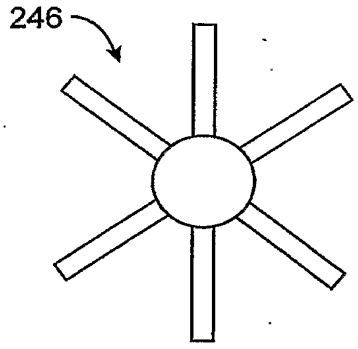

FIG. 18D

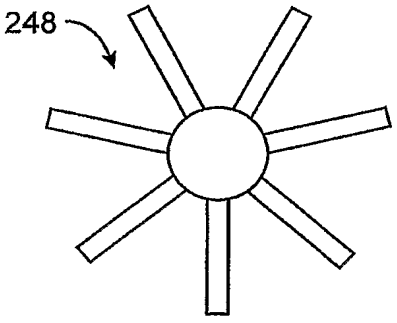

FIG. 18E

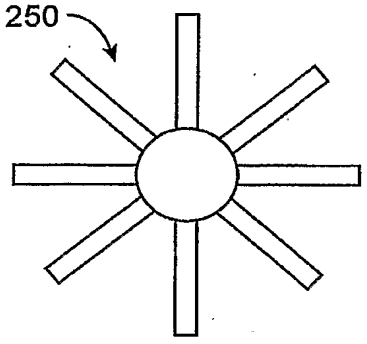

FIG. 18F

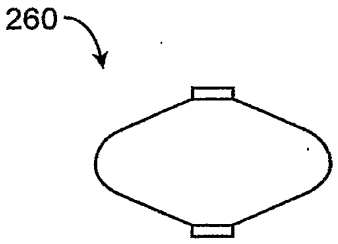

FIG. 19A

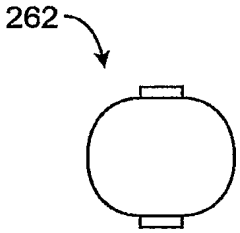

FIG. 19B

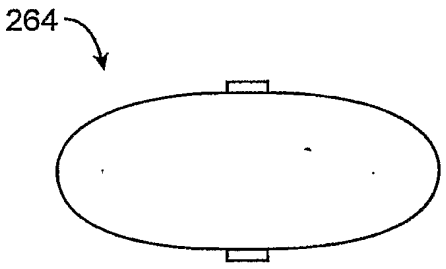

FIG. 19C

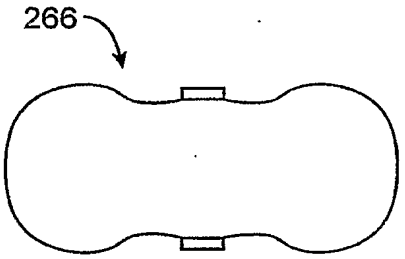

FIG. 19D

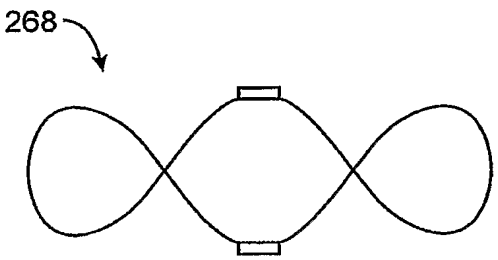

FIG. 19E

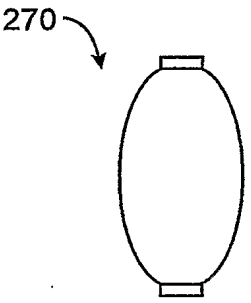

FIG. 19F

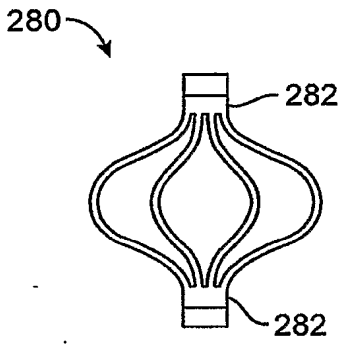

FIG. 20A

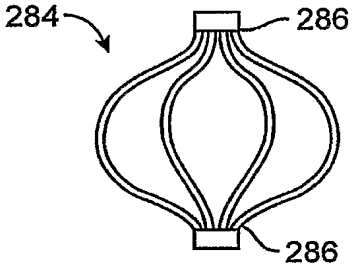

FIG. 20B

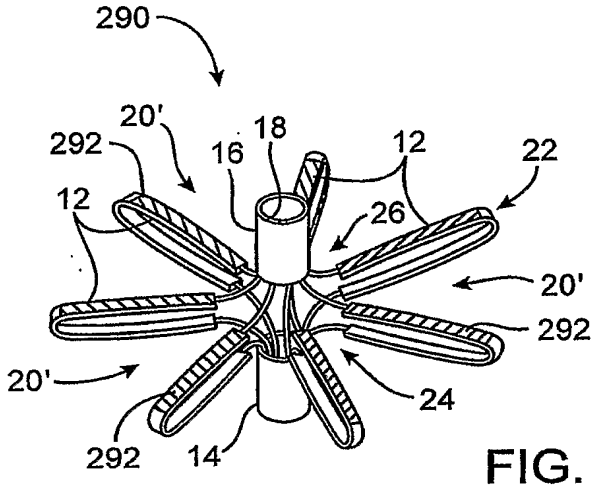

FIG. 21A

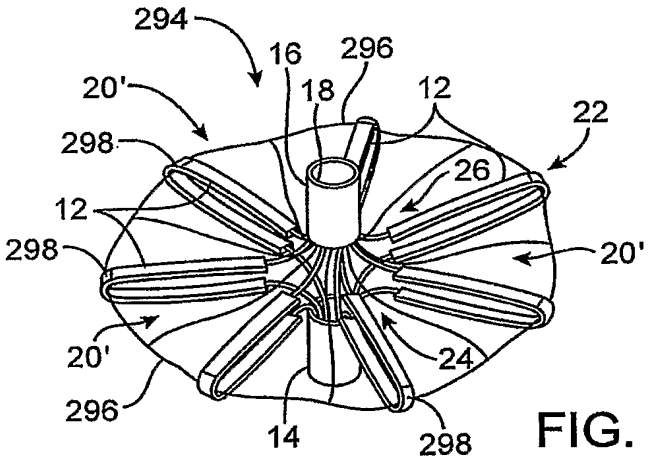

FIG. 21B

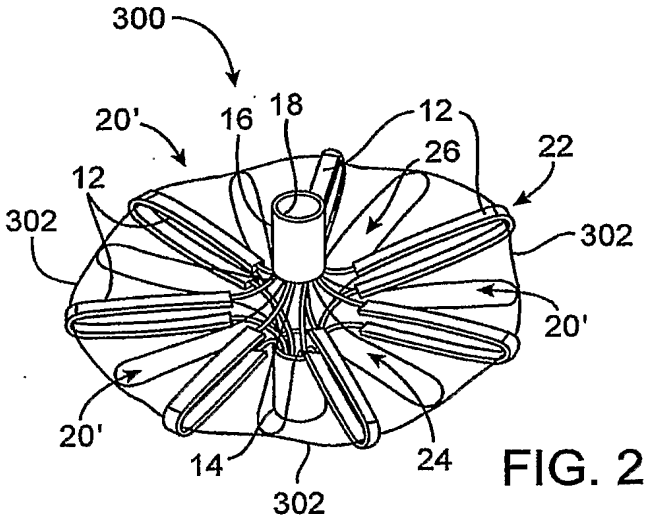

FIG. 21C